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10/679,900	10/06/2003	Mark A. Hoffman	CRNI.107060	3801

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EXAMINER	
CLOW, LORI A	
ART UNIT	**PAPER NUMBER**
1631	
MAIL DATE	**DELIVERY MODE**
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/679,900	**Applicant(s)** HOFFMAN, MARK A.	
	Examiner LORI A. CLOW	**Art Unit** 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2009*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-38 and 40-49* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *34-38 and 40-49* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 3 September 2009, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 34-38 and 40-49 are currently pending. Claims 1-33, 39, and 50-64 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 34-38 and 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claustres et al. (Genome Research (2002) Vol. 12, pages 680-688), in view of Scriver et al.

(Human Mutation (1999) Vol. 13, pages 344-350), for the reasons set forth in the previous Office Action and reiterated below.

Instant claim 34 is drawn to a computer system for documenting mutations including the following limitations:

a) receiving mutation information

b) disassembling mutation information into discrete elements, wherein the discrete elements include patient identification value, reference sequence identification, a starting point, and an ending point within the reference sequence

c) storing said discrete elements such that the mutation may be presented using both user-preferred standards and published standards

d) displaying the mutation using the user-preferred standard or the published standard

In regard to the above limitations, Claustres et al. teaches recommendations for a unified system of mutation description and reporting in locus-specific mutation databases. Claustres et al. specifically teach receiving mutation information (entire article). Claustres et al. specifically teach disassembling mutation information into elements that are both stored and presented to users. The information may be a patient identification number (page 682, Table 2; Table 4-Patient ID), reference sequence identification (Table 2-unique mutation ID), and starting and ending point information (Table 2-gene region search). Claustres further teaches the storage and display of information that include not only published standards, but also user-preferred standards (Table 2-HUGO-MDI nomenclature and other nomenclature; Table 4 HUGO name and trivial name).

Instant claims 35 and 46 include the limitation wherein the mutation information is for one of a substitution, inversion, deletion, translocation, complex rearrangement, and combinations thereof.

Claustres et al. teach that any type of mutation information may be represented (Table 4-search by mutation column).

In regard to claim 36 that includes limitations on the discrete elements that include one or more of mutation identification. Patient identification etc…, Claustres teaches mutation identification and patient identification, at least, at Table 4.

In regard to claims 37, 47, and 48 with the limitation of defined user-standards, Claustres teaches user standards at Table 4.

Claims 38 and 49 require that the published standards be those of HUGO. Claustres teaches HUGO standards at Table 4.

In regard to claim 40, Claustres teaches known mutations for particular sequenced genetic information at Table 4 (genetic locus, chromosome location etc.)

In regard to claim 41, the sequenced information is from a gene (Table 4).

In regard to claim 42, Claustres teaches known mutations at page 681, Table 1, which lists known mutations.

In regard to claims 43 and 44, Claustres teaches reference sequence information at Table 4.

In regard to claim 45, Claustres teaches data entry fields (Table 4).

Claustres et al. do not specifically teach the various modules for performing the recited steps. However, Scriver et al. teach guidelines and recommendations for building such databases so that each database may be specialized according to specific needs (abstract). Scriver teaches that software and deployment recognize the different needs of specialized and generalized databases (abstract). Scriver et al. further teach that there is no single correct way to design a database and that one can decide on concepts and how to divide into certain desired fields and assign different attributes of operability (page 347, column 2). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to employ the ideas of Scriver et al. to design a unique database with the recommendations about ideal databases as set forth in Claustres et al. One would have been motivated to do so, as discussed above, because Scriver et al. teaches the benefit in doing so. One would have had a reasonable expectation of success, as database structure and design, as well as the specifics of different mutation databases and database requirements were well known. One of skill in the art could merely have combined such teachings to create the ideal mutation database.

Response to Applicant's Arguments

1. Applicant argues that "neither the Claustres nor Scriver references teach or suggest selecting one of a set of user-preferred and published standards and displaying a mutation in accordance therewith".

This is not persuasive. Claustres teaches these embodiments, as stated above in the instant rejection. Further, Claustres teaches in the abstract that the systems are implemented such that mutation information is collected and displayed to the public (abstract). The systems disclosed contain user-interfaces to all genes with pooled information on variations across genomes (page 680, column 1). Further, Claustres teaches that some databases contain user standards and some databases contain published standards, such as the HUGO-MDI format (page 681, column 2; page 682, Table 2; page 683, column 2). Therefore, Claustres teaches selecting a user-preferred or a published standard for display of the mutation information in the said databases.

2. Applicant states that Scriver et al. "does not teach or fairly suggest receiving a selection of one of the user-preferred and published standards”

This is not persuasive, as it is Claustres that is relied upon to teach the elements recited. Further, Scriver et al. teach the use of HUGO standards in the content of mutation databases (page 344, column 1), as well as nomenclature guidelines for naming alleles etc… (page 345, column 2).

3. Applicant argues that “neither the Claustres nor Scriver references teach or suggest assembling mutation information using discrete elements in accordance with the selected user-preferred or published standard".

This is not persuasive. As is stated above and further emphasized, Claustres teaches discrete elements in databases at page 681, column 2 (data entries and gene, protein and disease information) and at Table 2 listing mutation content. Further, Scriver teach that selection of range and data types within a database will depend on context in which the mutation are collected and that essential and optimal content is included (page 346, column 1). Further, the mutation information can be presented according to standards of either that observed by many experiments or by just one experiment (user standard or presumably a Published standard) and assembled to include exact sequences of the region explored and may include other complex data (page 346, column 2, bottom to page 327, column 1).

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 15, 2009
/Lori A. Clow, Ph.D./
Primary Patent Examiner
Art Unit 1631